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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,439	RICHARDSON ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 31-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-69 are pending in this application and are the subject of the Office action.

Restriction/Election Requirement

Applicant's election of the group I (i.e. claim 29) with traverse is acknowledged and made of record. Applicant's argument that claim 30 ought to be examined along with claim 29 in view of the fact that six of the eight ingredients encompassed by both claims are the same and would not present an increased search burden to the examiner is deemed persuasive. Thus, the restriction requirement with respect to group II (i.e. claim 30) is withdrawn.

Claims 1-28 and 31-69 are withdrawn from further consideration for examination purposes for being directed towards non-elected subject matter.

Claim Rejections – 35 USC 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a layered tablet comprising an immediate-release layer and a sustained-release layer having synergistic anti-herpes viral activity (see Example 2, page 16, line 15 to page 18, line 21). However, the

disclosure of the instant application does provide enablement for a layered tablet having additive anti-herpes viral activity. Thus, the instant disclosure provides inadequate disclosure to reasonably provide someone of skill in the art on how to practice the instant invention commensurate with its scope without undue experimentation. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman* 230 USPQ 546 (BdApls 1986) at 547 the court cited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The instant invention is generally directed towards a layered tablet for the treatment of herpes simplex and conditions giving rise thereto comprising an immediate-release layer and a sustained release layer. Applicant asserts that the instant invention resides in a unique, orchestrated pharmaceutical formulation for use in the treatment of HSV-1 and HSV-2 that takes advantage of the additive and synergistic antiviral complentarity of these biofactors in a variety of applications and makes these specific formulations available in a variety of dosage forms (page 9, lines 16-19). Applicant asserts that upon oral ingestion of the layered tablet, agents of the immediate release layer dissolve rapidly in the stomach and are available for immediate absorption in the

gastrointestinal tract (page 18, lines 9-11). The polymer matrix of the controlled release layer does not dissolve in the acid pH of the stomach, but remains intact until it passes to the upper part of the small intestine, where the enteric coating dissolves in the more alkaline environment of the intestine; the agents incorporated in this layer are then available for intestinal absorption as they osmotically diffuse from the water-swollen gel that is formed as the polymeric matrix immediately begins to imbibe water from the intestinal fluid (page 18, lines 9-17). Applicant further asserts that since the agents have been selected with a view toward their water solubilities, the rate of diffusion of each agent is reasonably constant for the useful life of the matrix (approximately four hours), by which time the incorporated agents are finally depleted and the matrix disintegrates (page 18, lines 17-21). The instant application does not disclose any data regarding the intended synergistic anti-herpes virus activity that is intended to be achieved in practicing the instant invention. Also, applicant does not disclose the specific amounts of the multiple active ingredients in the layered tablets or the relative amounts of each active ingredient to achieve a synergistic effect for the treatment od herpes simplex and conditions giving rise thereto.

Richardson et al. (U.S. Patent 6,207,190) teach that some ions, heavy metals or biomolecules may enhance or inhibit the gastrointestinal absorption of others and that substantial data is not available regarding this competitive absorption (column 14, lines 23-26). Richardson et al. also teach that zinc supplementation with even a moderate amount of Zn+2 has a detrimental effect on Cu+2 levels (column 16, line 64 to column 17, line 29). Richardson et al. teach pharmaceutical preparations for use as dosage

forms, transmembrane delivery or electrophoretic forms (column 6, lines 21- 23). The compositions and dosage forms are useful for treating glaucoma (column 24, lines 16-17). The preparations contain specific therapeutic biofactors and biomolecules selected because of their particular and critical physiological effects, which are combined in highly defined groups and amounts to achieve maximum complementarity of action (column 6, lines 23-27). Richardson et al. disclose compositions, formulations and dosages of primary components including magnesium L-ascorbate, N-acetylcysteine (NAC); Quercetin selenium, l-cysteine, copper sulfate (column 14, line 43 to column 17, line 38). Richardson et al. teach dosage forms of a single layer tablet substantially homogeneous that releases all of its components into the stomach upon ingestion, a sustained dosage form, and tablet dosage form where both the immediate release and the sustained release dosage forms are combined into a bilayer tablet (column 22, lines 52-57. Richardson et. al. also teaches delivery vehicles that inherently retard the release rate (column 21, line 63 to column 22, line 51). Richardson et al. teach N-acetyl-cysteine (NAC), mercaptopropionylglycine (MPG) or l-2-oxothiazolidine-4-carboxylate (OTC) may be include in this invention as a free base or combined with the metallic cations (column 19, lines 40- 56). Richardson et al. teach that taurine may be used in its free forms or complexed or both (column 20, lines 41-45). Richardson et al. teach magnesium present either as Mg+2 salts or Mg+2 complexes that release magnesium ion when ingested, or both e.g. salts that can be used – acetate, acetyl-cysteinate, arginate, ascorbate, cutrate, lipoate, malate, oxide, stearate, sulfate and taurate (column 20, lines 46-51). Richardson et al. also teach that magnesium stearate

is useful as a lubricant when compressing the composition into tablets, in addition to its use as a minor Mg +2 source (column 20, lines 65-67). Richardson et al. teach copper present either as Cu+2 salts or Cu+2 complexes that release copper ion when ingested, or both e.g. arginate, lipoate, sulfate, and taurate (column 21, lines 4-10). Richardson et al. teach zinc present either as Zn+2 salts or Zn+2 complexes that release zinc ion when ingested, or both e.g. acetate, lipoate, sulfate, and taurate (column 21, lines 11-17). Richardson et al. teaches selenium present either as Se+2 salts or Se+2 complexes that release selenium ion when ingested, or both e.g. acetate, arginate, lipoate, sulfate, and taurate; L-selenomethionine is a preferred source of Se+2. Richardson et al. teach ascorbate present in either ascorbic acid, metalloascorbate salts or complexes of ascorbate, or all of these e.g. metallic salts include Mg+2, Cu+2 or Zn +2 and that Quercetin and vitamin B vitamins may be present in their free forms (column 21, lines 58-62). Richardson et al. discloses that the recitation of any component as a metal without specifying a charge or oxidation state in the disclosure includes the metal in ionized form such as in a salt or bound form such as in an oxide or other chemical compound (column 7, lines 15-19). Richardson et al. teach that N-acetylcysteine (NAC) is a glutathione (GSH) precursor (column 7, lines 44-65).

Jones et al. (U.S. Patent 6,013,632) teach that a variety of known compounds are effective for the prevention and treatment of influenza virus infection and that treatment with glutathione (GSH), glutathione disulfide (GSSG), N-acaryl-L-cysteine or ascorbate-2-phosphate, or any combination thereof, with or without antioxidants is

suitable for the prevention or treatment of influenza virus infection (column 1, lines 27-34). Jones et al. teach that N-acetyl-L-cysteine is known as a disinfectant for Hepatitis B virus, an agent that enhances the response of interferon-alpha in chronic Hepatitis C cases, a mucolytic agent, functions as a reducing sulfur compound in certain protein purifications, functions as an agent for treating lower respiratory tract infections in children, chronic bronchitis, HIV infection, chronic cardiorespiratory disorders and fulminant hepatic failure (column 2, lines 11-17). Jones et al. teach that Vitamin C is widely used as an ingredient of cosmetic compositions as well as a common dietary supplement (column 2, lines 31-42). Jones et al. teach pharmaceutical compositions useful in preventing or treating of influenza virus infection comprising a) one or more compounds selected from the group consisting of glutathione, glutathione disulfide, ascorbate-2-phosphate and N-acetyl-L-cysteine, or a pharmaceutically acceptable salt of any of these compounds; b) one or more antioxidants selected from the group consisting of vitamin A, vitamin E, vitamin K, copper (as cupric oxide), zinc (as zinc oxide), iron (as ferrous salt), selenium (sodium selenate), beta-carotene, polyphenol, catechin, quercetin, eriodictyol, carnosic acid, carnosol, rosemarrinic acid, caffeic acid, coumaric acid, cinnamic acid, Coenzyme Q10, Probucol, astaxanthin, lycopene, alpha-lipoate, and urate, or pharmaceutically acceptable salt of any such antioxidant; and c) a pharmaceutically acceptable carrier (column 3, line 26 to column 4, line 59). Jones teach that the compositions may be administered orally, nasally, or rectally, in dosage unit formulations containing conventional non-toxic pharmaceutically-acceptable carriers, adjuvants and vehicles (column 9, line 66 to column 9, line 3).

Fahim (U.S. Patent 4, 937,234) teaches that metals are highly charged molecules such that many minerals are not absorbed well and do not pass into cells easily even if available in the serum; (column 1, lines 28-30). For example, oral administration of a zinc supplement, such as zinc sulfate, zinc chloride or zinc acetate increases the zinc concentration in the serum but does not consistently increase the zinc concentration in the seminal plasma and improve prostate function even though the prostate is the organ of man that is richest in zinc and zinc concentration in seminal plasma serves as an indicator for prostate function (column 1, lines 30-38). Fahim teaches that minerals such as zinc and magnesium are involved in certain enzymes and are essential for maintenance of life in man, animals and plants (column 1, lines 8-11). Fahim teaches that in some instances vitamins facilitate the incorporation of the mineral into the enzyme such that enzyme activity is inhibited by a shortage in the mineral or in the vitamin (column 1, lines 11-14). Fahim teaches that lysine, arginine and histidine are basic amino acids (positively charged at pH 6) and might be used to neutralize the acidity of zinc salts such as zinc acetate, zinc chloride and zinc sulfate (colum 1, line 66 to column 2, line 2). Fahim teaches minerals salts of carboxylic acid derivative of a pentose or hexose such as zinc gluconate or zinc gulonate neutralized in the presence of certain amino acids to provide minerals in bioavailable form which are absorbed more readily and act more efficiently on the cellular level in the target organ than the mineral alone; this is accomplished without compromising the bacterial effect of the zinc that has been thought to be due in at least in part to the acidity of the zinc salt (column 2, line 29 to column 3, line 25). Example 12 discloses a composition comprising zinc

ascorbate (2% by weight) and lysine (2% by weight) (column 8, lines 27-48). Example 13 teaches a method for preparing zinc ascorbate (column 8, line 59 to column 9, line 2). Fahim discloses that other minerals which may be administered in the subject form include calcium, iron, magnesium, manganese and the like (column 2, lines 35-37).

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. It is noted that the pharmaceutical and therapeutic arts are generally unpredictable, requiring each embodiment to be individually assessed for physiological activity. The more unpredictable an area, the more specific enablement is necessary in order to satisfy the statue. (see *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)).

In view of the teaching of Richardson et al. teach that some ions, heavy metals or biomolecules may enhance or inhibit the gastrointestinal absorption of others and that substantial data is not available regarding this competitive absorption, coupled with the fact that zinc supplementation with even a moderate amount of Zn+2 has a detrimental effect on Cu+2 levels, someone of skill in the art would reasonably not be able to predictably practice the instant invention without undue experimentation.

2. <u>The breadth of the claims</u>

The claims are very broad. Claim 29 is very broad as it recites the limitation "conditions giving rise thereof," which given its broadest reasonable possible interpretation would reasonably encompass any other condition. Claim 30 recites the term "for use as an oral dosage form," which reasonably encompass its use for treating any condition, including herpes simplex. Also, both claims encompass a large

heterogenous group of species who could reasonably be treated with the instant invention. Because the therapeutic effects to be achieved by administering the bi-layered tablet would necessarily vary depending upon the intended condition, or the particular species, to be treated, the level of predictably in practicing the claimed invention would be greatly diminished.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no specific direction or guidance for using the instant invention to achieve a synergistic anti-herpes effect and no working examples are disclosed except for Example 2, which provides a simple listing of the active ingredients.

4. The quantity of experimentation necessary

To reiterate, in view of the teaching of Richardson et al. teach that some ions, heavy metals or biomolecules may enhance or inhibit the gastrointestinal absorption of others and that substantial data is not available regarding this competitive absorption, coupled with the fact that zinc supplementation with even a moderate amount of Zn+2 has a detrimental effect on Cu+2 levels, someone of skill in the art would reasonably not be able to predictably practice the instant invention commensurate with its scope without undue experimentation.

For the reasons stated above, claims 29-30 are rejected under 35 USC 112, first paragraph, for lack of enablement because the specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate disclosure of the instant application.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 30 are rejected under USC 103(a) as being unpatentable over Jones et al. (U.S. Patent 6,013,632), Murad (U.S. Patent 5,804,594), in view of Richardson et al. (U.S. Patent 6,207,190).

The discussion of Jones et al. in connection with the above 112, 1st paragraph, scope of enablement rejection is incorporated by reference. To summarize, Jones et al. teach that a variety of known compounds such as glutathione (GSH), glutathione

disulfiede (GSSG), N-acaryl-L-cysteine or ascorbate-2-phosphate, or any combination thereof, with or without antioxidants are suitable for the prevention or treatment of influenza virus infection (column 1, lines 27-34). Specifically, Jones et al. teach various antioxidants including copper, zinc, selenium, quercetin, or pharmaceutically acceptable salt of any such antioxidants (column 3, line 26 to column 4, line 59).

Murad discloses a topical composition for the treatment of herpes simplex, cold sores, lesions, and other painful skin conditions including L-lysine; the composition may also include L-ascorbic acid (column 2, lines 20-52). Murad also discloses that the pharmaceutical compositions are suitable for oral administration as discrete units such as capsules, cachets, or tablets (column 9, lines 33-40). Example 3 teach a table comprising various active ingredients including N-acetylglucosamine (17.7 % w/w), vitamin C (15 % w/w), L-lysine (12.2 % w/w), D-Glucosamine sulfate (6.5 % w/w), zinc monomethionine (3.5 % w/w) , N-acetyl cysteine (3.7 % w/w), Quercetin powder (2.4 % w/w), selenomethionine (0.5 % w/w), copper sebacate (0.4 % w/w)(column 10, lines 35-66). Thus, someone of skill in the art at the time the instant invention was made would have been motivated to combine the teaching of Jones et al., in view of Richardson et al., in view of Murad to create a layered tablet of the instant ingredients to treat herpes simplex.

Majeed et al. (5,744,161) is being added to show the general state of the art. Majeed et al. teach preparations and methods of using certain preparations to improve the bioavailability of various nutritional compounds (column 5, lines 42-45). The

compositions may include any nutrient, biological compound, or nutritional supplement, water soluble vitamins, fat soluble vitamins, amino acids (i.e. lysine and methionine), essential minerals (e.g. zinc, cooper, magnesium), and antioxidants (e.g. vitamin C, vitamin A, vitamin E, selenium, zinc) (column 6, line 66 to column 8, line 5). For example, Majeed et al. disclose a nutritional formulation comprising vitamin C, zinc (monomethionine), selenonium (L-Selenomethionine), Quercetin, L-taurine, and other active ingredients (column 9, lines 46-58).

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success in view of the teaching of Jones et al., in view of Richardson et al., and further in view of Murad.

Claim rejections – 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claim 29 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses herpes simplex, which meets the written description

and enablement provisions of 35 USC 112, first paragraph. However, claim 29 is directed to "conditions giving rise thereto" which only correspond in some undefined way to specifically instantly disclosed herpes simplex. None of these "conditions giving rise thereto meet the written description provision of 35 USC § 112, first paragraph, due to lacking structure/function information or specific etiological data for what they are medical conditions are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

> "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above herpes simplex, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable overs claim 4 and 12 of U.S. Patent (6,207,190), in view of Jones et al. (U.S. Patent 6,013,632), and further in view of Murad. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims.

In particular, reference claims 4 and 12 are directed to a unit dosage form bilayer tablet comprising an immediate-release layer and a sustained-release layer, wherein the active agents are distributed in the following approximate proportions expressed as weight percents (column 25-26):

	Immediate-Release	Sustained-Release

L-arginine	75%	25%
N-cetyl-cysteine	75%	25%
Folic acid	100%	
Magnesium	40%	60%
Taurine	70%	30%
D,α-tocopherol	100%	
Ascorbate	50%	50%
Selenium	100%	

Reference claim 12 recites Zn+2 and Cu+2 as constituents of the bilayer.

The above discussion of Jones et al., Richardson et al., and Murad with respect to the 103(a) rejection is incorporated by reference. To the extent that the reference claims recite the term "comprising," it is reasonably contemplated that additional active ingredients may be added to the composition. Thus, someone of skill in the art at the time the instant invention was created would have deemed it obvious to create the instant invention with a reasonable expectation of success in view of Jones et al., in view of Richardson et al, and further in view of Murad.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 8 a.m. to 4:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Ardin H. Marschel 3/5/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER